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March 28, 1989

#15

Mr. Ronald Wilson
Office of the Associate Commissioner
for Health Affairs (HFY-20)
Room 11-46
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Nimotop
FDA Docket # 89E-0104

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for Patent Term Extension of U.S. Patent No. 4,406,906 issued September 27, 1983. The application was filed on February 24, 1989 under 35 U.S.C. § 156.

The patent claims a process of using a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination of the applicable regulatory review period is necessary.

Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A) for a determination of the length of the regulatory review period.

C.E. Van Horn

Charles E. Van Horn
Deputy Solicitor
Patent and Trademark Office

cc: Louis E. Davidson
Miles Inc.
P.O. Box 40
Elkhart, IN 46515